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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

RANCHERS CATTLEMEN ACTION LEGAL FUND UNITED STOCKGROWERS OF AMERICA, Plaintiff, vs. UNITED STATES DEPARTMENT OF AGRICULTURE, et al., Defendants.	CV 05-06-BLG-RFC DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION TO SET MOTIONS FOR SUMMARY JUDGMENT FOR ARGUMENT

INTRODUCTION

The Ninth Circuit's message has been loud and clear in this case, and a ruling on the merits should now be entered in defendants' favor. Plaintiff alleges that the Ninth Circuit blindly accepted the agency's rule in ignorance of the facts. In view of the 12,560-page Administrative Record and reams of briefs, declarations, and exhibits before that Court, and the panel's comprehensive and thoughtful decision, nothing could be further from the truth. Plaintiff's captious arguments neither deserve further debate nor warrant second-guessing the Ninth Circuit's conclusions as to the merits. Moreover, it would be pointless to hold oral argument so that the parties could debate the import of Japanese beef under a different rule, or FDA's proposal to improve the feed ban in the United States due to a finding of BSE in a Texas cow. These two rulemakings are completely irrelevant to this case. Furthermore, to re-argue issues which have already been discussed ad nauseum in briefs and declarations submitted to the Court over the past year – issues which were considered by the Ninth Circuit – would be a waste of the Court's resources. In short, oral argument for the reasons cited by plaintiff should be denied.

ARGUMENT

1. Plaintiff Fails to Show Oral Argument Is Necessary, and the Need for Oral Argument Is Committed to the Court's Discretion

The Court has discretion to decide whether oral argument would serve any useful purpose, especially given the exhaustive briefing of all relevant issues by both parties and the Court's familiarity with them. See Fed. R. Civ. P. 78; Local Rule 7.1(h); see, e.g., Intermountain Adm'rs v. Neal, No. 94-CV-5, 1998 WL 34312895, *4 (D. Mont. Sept. 30, 1998); Aetna Cas. & Sur. Co. v. First Sec. Bank of Bozeman, 662 F. Supp. 1126, 1127 n.1 (D. Mont. 1987). Contrary to plaintiff's claim, Memorandum in Support of Plaintiff's Motion to Set

Motions for Summary Judgment for Argument ("Pl. Memo.") at 2, Fed. R. Civ. P. 56 does not require oral argument – or even mention it. Plaintiff's motion to set argument is a transparent attempt to supplement its summary judgment motion without leave of Court. See Local Rule 56.1(d) (stating that the parties "shall file no further factual materials except with leave of the Court" upon filing of the Statement of Undisputed Facts and Statement of Genuine Issues); Local Rule 7.1 (g) (stating that following the reply brief, "[n]o further briefing shall be allowed without leave of Court"); see also Johnson v. Hertz Local Edition Corp., No. C 03-4439 MJJ, 2004 WL 2496164, *3 n.3 (N.D. Cal. Nov. 3, 2004) (holding that a party cannot file additional material to supplement its motion for summary judgment without leave of court). It also invites the Court to improperly consider matters far outside the Administrative Record. See Feb. 23, 2005 Order Denying Motion of the Gov't of Canada for Leave to File Brief Amicus Curiae (rejecting as "inappropriate" a filing that "purports to add facts . . . which presumably are not in the record," or that "purports to provide new information about recent developments"); Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co., 463 U.S. 29, 50 (1983) (stating that the Final Rule must be assessed "on the bas[es] [already] articulated by the agency" in promulgating the rule); The Hopi Tribe v. The Navajo Tribe, 46 F.3d 908, 915 (9th Cir. 1995) (finding that the Court's role is to assess whether the rationale stated by the agency is based on a reasonable weighing of the evidence in the Administrative Record). For these reasons alone, plaintiff's motion should be stricken or disregarded. See, e.g., Leong v. Potter, 347 F.3d 1117, 1125 (9th Cir. 2003) (upholding district court's enforcement of procedural rules by striking of supplemental brief that was filed late and without permission); Friends of the Earth v. Hintz, 800 F.2d 822, 828 (9th Cir. 1986) (upholding the district court's quashing of deposition notices because discovery would

have impermissibly expanded the administrative record).[1]

But aside from flouting the rules, plaintiff takes facts out of context, reargues issues already carefully considered by the Court of Appeals, picks nits over nonexistent inconsistencies, and draws inapposite conclusions regarding the rule governing the importation of boneless Japanese beef into the United States, and a recently issued FDA proposed rule to improve the domestic feed ban. Its motion ignores the twenty years of science that lie behind the rule, and in doing so, distorts and misrepresents the true facts that this Court should consider. There is no point in holding an oral argument on any of the matters plaintiff raises.

2. The Court of Appeals for the Ninth Circuit Correctly Understood the Facts

The Court of Appeals for the Ninth Circuit considered all the relevant facts, understood them correctly, and reached the right decision. While the Ninth Circuit obviously did not purport to issue a final decision on the merits of the case, see Pl. Memo. at 2, it clearly and necessarily considered the merits when it determined whether the preliminary injunction was warranted. Hence, the Ninth Circuit conducted its "own review of the Final Rule," RCALF v. USDA, 415 F.3d 1078, 1095 (9th Cir. 2005), examined all of the BSE safeguard measures underlying the Rule, id. at 1095-96, and considered each of the six specific grounds for this Court's finding that the Final Rule was arbitrary and capricious, id. at 1096-1100, as well as the other arguments raised by plaintiff, id. at 1100-1104. The Court of Appeals concluded "that the Final Rule will

[1] See also Save Our Bays & Beaches v. City & County of Honolulu, 904 F. Supp. 1098, 1107 n.10 (D. Haw. 1994) (disregarding supplemental brief filed without leave of court) ; In re Century 21-RE/MAX Real Estate Adver. Claims Litig., 882 F. Supp. 915, 920 (C.D. Cal. 1994) (striking all unauthorized supplemental briefs); Chan v. Orthologic Corp., No. Civ 96-1514 PHX RCV, 1998 WL 1018624, *7 n.5 (D. Ariz. Feb. 5, 1988) (striking unauthorized supplemental briefs and noting that where the court already has hundreds of pages of briefing before it, it is not required to accept more); Zack v. Allied Waste Indus., 2005 WL 3501414, *1 (D. Ariz. Dec. 15, 2005) (striking unauthorized supplemental brief).

likely survive judicial scrutiny under the correct legal standard," and that plaintiff "has not shown a likelihood of success on the merits of its action." Id. at 1105.

The notion that the Ninth Circuit did not have a complete record before it, Pl. Memo at 4, or that there was an "incomplete development of the facts," Pl. Memo at 6 n.3, is simply false. It was wholly unnecessary to submit an Administrative Record to the Court before the Rule became final in January 2005 and before plaintiff filed this action to preliminarily enjoin its implementation. Nonetheless, defendants did compile the 12,560-page Administrative Record and file it with the Court on February 18, 2005, before plaintiff filed its reply brief and before the March 2, 2005 hearing on its preliminary injunction motion. The Ninth Circuit stated that despite the "remarkably expedited schedule" on which the case proceeded, "we have the benefit of a detailed record that demonstrates USDA's precise course in this action." RCALF v. USDA, July 25, 2005 Memorandum, No. 05-35214, at 6 (9th Cir.) (denying intervention to NMA and CCA/ABP); see also id. (noting that "USDA has provided detailed arguments"); id. at 7 (calling the record "well-developed"). The Ninth Circuit also noted that the agency had "considered 3,379 comments from interested parties," 415 F.3d at 1089, which were included in the Administrative Record. Thus the decisions in this case were based on a full panoply of relevant facts and a complete record.

The unsubstantiated claim that the Ninth Circuit erred on the facts, Pl. Memo. at 6 n.3, is really just one more expression of plaintiff's disagreement with USDA's rule and the Ninth Circuit's conclusions as to the facts rather than a demonstration that those facts were wrong. Indeed, if the Ninth Circuit had any doubt about the correctness of its decision, it could have granted plaintiff a rehearing – which it flatly declined to do. Plaintiff's allegations of error amount to nothing more than quibbling over facts already considered and arguments already

rejected by the Ninth Circuit. Those unfounded allegations provide no basis for further oral argument and certainly do not warrant a rejection of the Ninth Circuit's view as to the merits of this case.

For example, plaintiff makes another pitch for the notion that the Rule is invalid in the absence of a quantitative risk assessment. Pl. Memo. at 5 n.2. Yet the Ninth Circuit expressly held that the "district court's imposition of . . . a bright-line prohibition on qualitative standards was incorrect," 415 F.3d at 1096-97, and that "the [Animal Health Protection Act] does not require the Secretary to quantify a permissible level of risk or to conduct a risk assessment," id. at 1097. Moreover, the document to which plaintiff points, AR009519-009529, which was available to the Ninth Circuit, is a guidance document published on APHIS's website which generally describes the regionalization process and how it applies risk analysis to evaluate the status of regions that wish to export animals or animal products to the United States. As that document points out, assessments may be either qualitative or quantitative and the choices made within APHIS depend on the underlying disease risk in the region. As the document also points out, quantitative modeling is not required, but may occur to address specific risks or risk mitigation measures. The document states that regions requesting to be considered free of a disease have "historically" been considered qualitatively, while requests to export a specific product have "historically" been approached quantitatively. This website guidance is consistent with USDA's risk assessment of Canada as a region and with the risk associated with imports from Canada. Nothing in the document can be construed as a commitment or requirement to conduct quantitative risk assessments in every situation.

Similarly, there is nothing in the Animal Disease Risk Assessment, Prevention, and Control Act of 2001, which requires a quantitative risk assessment. See Pl. Memo. at 5 n.2.

That statute merely required the Secretary to convene an inter-agency working group and submit a report to Congress within 180 days discussing certain issues relating to foot-and-mouth disease, BSE, and related diseases. The Secretary complied with the Act by submitting a report to Congress in 2002. This statute is not relevant to this case, and even if it were relevant, there is no showing that the Ninth Circuit was unaware of it, and in any event, plaintiff has not heretofore raised it in this litigation. See Pl. Memo. at 5 n.2.

Plaintiff's argument that the Ninth Circuit erroneously called the feed ban the "foremost" measure for preventing BSE in the United States, whereas USDA has deemed import restrictions to be the most important line of defense, Pl. Memo. at 6 n.3, is disingenuous. The critical point, recognized by the Ninth Circuit, is that both measures, appropriate science-based import restrictions and an effective feed ban, play a vital role in controlling BSE in Canada and the United States.[2] See 415 F.3d at 1095-96. Furthermore, both statements are correct. As the

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[2] It was announced on January 23, 2006, that a nearly-6-year-old cow in Alberta, Canada tested positive for BSE. Because the rule only allows imports from cattle under-30-months of age, the rule would have prohibited the import of this cow into the United States. 9 C.F.R. § 93.436. Canada is conducting an epidemiological investigation to identify, among other things, the source of the animal's feed. Statement by Chief Veterinary Officer John Clifford, Animal and Plant Health Inspection Service, Regarding BSE Find in Canada, Jan. 23, 2006, http://www.aphis.usda.gov/newsroom/content/2006/01/bsecan_statement.shtml. However, USDA remains confident in the animal and public health measures that Canada has in place to prevent BSE, combined with existing U.S. domestic safeguards and additional safeguards outlined in the rule. Id.; see 415 F.3d at 1095-96 (discussing "BSE prevention measures currently in place as part of a comprehensive system"); id. at 1098 (finding the trial Court's criticisms of Canada's feed ban "baseless"); id. at 1093-94 (finding that the District Court had "committed legal error by failing to respect the agency's judgment and expertise"). In this rulemaking, USDA necessarily considered the possibility of additional cases in Canada. AR 8098-8100; see also 415 F. 3d at 1094 ("[T]he AHPA [Animal Health Protection Act] does not impose any requirement on USDA that all of its actions carry no associated increased risk of the disease."). Even if an infected animal were to enter the United States, however, the "overlapping and complementary safeguards" in the regulatory system are designed eventually to eradicate it. 415 F.3d at 1096. The new case in Canada offers no reason for departing from that conclusion.

Ninth Circuit properly noted, a feed ban is the most effective measure to prevent the spread of disease once it has been introduced. 415 F.3 at 1087 (stating that "feed bans are generally the first line of defense against the spread of BSE, and they have been highly effective in other countries") (emphasis added). On the other hand, appropriate science-based import restrictions are most important in preventing its introduction. It is plaintiff's description and characterization of these two measures, rather than the Ninth Circuit's decision, which are in error.

Plaintiff also erroneously accuses the Ninth Circuit of being unaware that younger cattle can carry BSE without manifesting symptoms. Pl. Memo. at 6 n.3. The Ninth Circuit was clearly aware of this fact when it correctly stated that "BSE has an incubation period that lasts for four to five years on average . . . during which the animal carries the disease but shows no outward symptoms." 415 F.3d at 1086. Furthermore, insofar as plaintiff is implying that younger cattle with hidden infectivity pose a risk, the Ninth Circuit found that the removal of SRMs at slaughter prevents infected tissues from contaminating human food. 415 F.3d at 1088 n.7. Contrary to plaintiff's assertion, the Ninth Circuit had a very clear grasp of the epidemiology of BSE.

Plaintiff erroneously claims that the Ninth Circuit was wrong in stating that the vast majority of vCJD cases occurred during the height of the BSE epidemic in England, when the first case of vCJD did not appear until after the height of the epidemic. Pl. Memo. at 7 n.3. Plaintiff's assertion in this regard is a virtual fabrication. The Ninth Circuit opinion quite clearly did not mean to suggest that the "height of the epidemic" was a statistically calculated point in time. More importantly, it is abundantly clear that the Ninth Circuit understood the epidemiology of transmissible spongiform encephalopathies ("TSEs"), as indicated by its recognition that TSEs can have "an incubation period of months or years." 415 F.3d at 1085.

The Ninth Circuit also noted correctly that there has not been a case of vCJD linked to North American beef and that the prevalence of BSE in Canada is very low. See 415 F.3d at 1095 (noting that "Canada's already low rate of BSE is decreasing"); id. at 1096 (stating that "no case of vCJD has ever been attributed to Canadian beef").

According to plaintiff, the Ninth Circuit mistakenly relied on the conclusion of the Harvard Study as finding that SRM removal would reduce human exposure by 95%, when in fact this figure was based on the more extensive SRM removal requirements in the United Kingdom. Pl. Memo at 6 n.3. But it is plaintiff that is mistaken. Plaintiff misinterprets the Ninth Circuit opinion, which merely cites to the Harvard Study as evidence that SRM removal is an effective mitigation measure to protect public health. The Ninth Circuit relied on the entire Administrative Record, not just the Harvard Study, as a basis for finding that "USDA's conclusion that SRM removal is effective . . . had support in the administrative record." 415 F.3d at 1098; see Memorandum in Support of Defendants' Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment ("Def. SJ Memo.") at 19-20 (summarizing scientific data regarding SRM removal).

Finally, plaintiff mistakenly contends that the Ninth Circuit did not address alleged evidence that USDA considered a desire to have open trade with Canada and the financial impact on multinational meat packers. Pl. Memo. at 7-8. The Ninth Circuit did, in fact, address this point and ultimately rejected the District Court's conclusion that the agency had a "preconceived intention, based upon inappropriate considerations, to rush to reopen the border regardless of uncertainties in the agency's knowledge." 415 F.3d at 1090-91. Instead, the Ninth Circuit found that the rule was based on reasoned scientific judgment supported by data in the Administrative Record.

Moreover, as defendants have pointed out before, the Secretary's principal obligation under the Animal Health Protection Act is to take such measures as the Secretary determines are necessary to prevent the introduction and spread of animal diseases in the United States. 7 U.S.C. § 8303. As the Ninth Circuit correctly observed, "[i]t is also notable that open borders are a default under the AHPA, and the Secretary can close them only if 'necessary' to prevent livestock disease." 415 F.3d at 1095. It is clear that the Secretary must fulfill his responsibility and facilitate safe trade consistent with sound science. Therefore, it is plaintiff who is urging inappropriate action here. Given that the rule has a sound scientific basis, a determination made by the Ninth Circuit as well as the Secretary, plaintiff can be taken as urging its invalidation because it harms plaintiff's competitive position in the beef industry. To invalidate the rule on this ground would indeed be improper.[3]

3. Recent Developments Are Not Relevant to this Case and Provide No Reason for Conducting Oral Argument

Plaintiff argues that the minimal risk region rule should be invalidated because USDA has now authorized boneless beef imports from Japan. Pl. Memo. at 7. The rationale for the new rule allowing the import of Japanese beef cannot properly be litigated here or serve as a basis for invalidating the rule, which arises from an entirely different set of facts and circumstances. Furthermore, the notion that the Japanese boneless beef rule is inconsistent with the minimal risk

[3] Plaintiff argues that USDA has said a ban on imports from all countries with BSE is an essential defense. Pl. Memo. at 9. This is a gross mischaracterization of USDA's position. Furthermore, since the 1980's scientific knowledge about how to prevent the spread of BSE has increased vastly. Current science does not support banning all imports, and the rule sets forth the conditions under which certain products may be safely imported. Def. SJ Memo. at 5-7. Moreover, everything plaintiff cites in support of this argument, Pl. Memo. at 9 n.4, was part of the Administrative Record or otherwise available to the Ninth Circuit when it concluded that the rule is reasonable.

region rule is based on a comparison of apples and oranges. For example, plaintiff argues that with respect to the Japanese beef rule, USDA takes the position that SRM removal is the only mitigation measure necessary to protect consumers. Pl. Memo. at 10. In fact, SRM removal is the single most important factor in reducing the risk to humans from the consumption of beef products. Since boneless beef is the only commodity allowed to be imported from Japan, that rule understandably relies heavily on SRM removal as a vital mitigation measure.[4] On the other hand, for cattle, which are allowed to be imported from Canada under the minimal risk region rule, the feed ban is the most important safety measure to prevent the spread of BSE. The differences between the two rules stem from their different contexts and relative objectives. Contrary to plaintiff's claim, USDA has been consistent in its approach to BSE in both rules. If there is an inconsistency, an allegedly less rigorous Japan beef rule would hardly serve as a basis for invalidating a more rigorous minimal risk region rule. Plaintiff also misrepresents the facts in contending that SRM removal is the only BSE mitigation step in the Japan rule. Pl. Memo. at 10. The rule also contains limitations on slaughter methods, inspection requirements, and sanitary dressing procedure requirements.

Similarly, plaintiff claims that USDA has abandoned surveillance as a mitigation measure under the Japanese beef import rule. Pl. Memo. at 11. This, again, is sophistry and ignores the context in which the subject statements were made. Because surveillance does not itself reduce the risk of introducing or preventing the spread of BSE, it is not, technically speaking, a mitigation measure. However, APHIS has always maintained that a statistically valid

[4] On January 20, 2006, a shipment containing cuts of beef not allowed under the terms of Japan's trade agreement with the United States was exported to Japan from a New York processing firm. The beef conformed with all U.S. domestic food safety rules. It has no bearing on the question of imports from Canada.

surveillance plan is important in measuring the effectiveness of mitigation measures, such as a feed ban. This reasoning makes perfect sense when considering the disease status of a region, as was done in the minimal risk region rule. See, e.g., AR 8098 (APHIS states in preamble to final rule that "active surveillance must be conducted to ensure that prevention and control measures implemented by a country are providing adequate protection . . . ."). As with the agency's discussion in the preamble to the Japan rule quoted by plaintiff, Pl. Memo. at 11, USDA has consistently maintained that the testing of all bovines at slaughter is not a scientifically justified surveillance technique. See 415 F.3d at 1099-1100.

Furthermore, whether a country conducts adequate surveillance is essential in determining the disease status of a region (such as Canada). See 415 F.3d at 1100 (noting that "testing was best used to determine if BSE exists in a country"). The purpose of the minimal risk region rulemaking was to determine whether Canada could be considered a minimal risk region for BSE, and if so, what animals and products from that region could be safely imported into the United States. See 415 F.3d at 1089. By contrast, the Japan rule is commodity specific: APHIS was evaluating whether a single commodity – boneless beef – could be safely imported from Japan, *irrespective of the disease status of the country*. Therefore, a surveillance requirement was not incorporated into the Japan rule as a prerequisite because the commodity to be imported – boneless beef – is considered safe if certain other requirements are met.[5]

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[5] This approach is consistent with the new OIE chapter on BSE, adopted in May 2005, which does not recommend any BSE related restrictions in the trade of deboned skeletal muscle meat derived from cattle under 30 months of age, regardless of the BSE status of the exporting region. For regions of more than negligible risk, the OIE guidelines recommend trade in beef if the cattle were not subjected to air-injection stunning or pithing and received ante-mortem and post-mortem inspections; the beef does not contain SRMs or mechanically separated meat from the skull or vetebral column of cattle over 30 months old; and the SRMs were removed in an manner to avoid cross-contamination. www.oie.int/downld/sc/2005/bse_2005.pdf. All of these

Plaintiff also argues that the minimal risk region rule should be invalidated based on another matter which is neither analogous nor informative: FDA's proposed rule to strengthen the feed ban. Pl. Memo. at 12. Plaintiff's argument that FDA's proposal to strengthen the feed ban indicates that the current U.S. feed ban is not effective, Pl. Memo. at 12, is specious.[6] Just because the feed ban can be improved, or because FDA has proposed to strengthen it based on finding BSE in a Texas cow, does not establish in any sense that the U.S. feed ban is ineffective, or more to the point, that the minimal risk region rule is arbitrary and capricious. On the contrary, the scientific data unequivocally show that the feed ban is very effective both here, 415 F.3d at 1096, and in Canada, id. at 1098-99. USDA never assumed that the feed ban was 100% perfect, but rather, that it was very effective both in content and in practice. Furthermore, the domestic feed ban is but one of several overlapping, sequential mitigation measures which, taken as a whole, reduce any risk to an inconsequential level. See 415 F.3d at 1095-96 (describing "overlapping and complementary safeguards" which "effectively" minimize the risk of BSE).

Plaintiff's argument that there are known loopholes in the U.S. feed ban, Pl. Memo. at 12, is a mischaracterization. There are certain materials and practices not currently covered which, some believe, should be prohibited by revised feed ban regulations. Whether these materials or

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measures were incorporated as requirements into the Japan rule. 70 Fed. Reg. 73905-73919.

[6] Plaintiff takes out of context FDA's statement that banning SRMs reduces human exposure by 80% and APHIS's statement that it reduces human exposure by 95%. See Pl. Memo. at 13-14. Taken in their proper context, the statements are consistent. APHIS's conclusion was based on the Harvard study, which analyzed the effect of relatively broad SRM removal requirements. See, e.g., Pl. Memo. at 6 n.3 (noting the "much more extensive SRM removal requirements" on which the Harvard study was based). On the other hand, FSIS modified the Harvard model to study the effects of a narrower range of SRM removal requirements along with the introduction of BSE into the system and delayed mitigation measures. Therefore, the difference between the two numbers merely reflects the different data put into the mathematical model.

practices constitute "gaps" or "loopholes" is the very issue to be determined in the FDA rulemaking. While the Court of Appeals noted that there are alleged gaps, see 415 F.3d at 1087, the minimal risk region rule took these issues into account, cf. 415 F.3d at 1095 (finding that the "cumulative effects of the multiple, interlocking safeguards" must be evaluated) (emphasis added). Moreover, FDA consulted with USDA and reviewed and approved the minimal risk region rule. Accordingly, FDA's proposed rule to amend the feed ban, see Pl. Memo. at 12, does not render the minimal risk region rule arbitrary and capricious.[7]

In arguing that other developments show that there is not an "impenetrable barrier" to BSE from imports, Pl. Memo. at 15, plaintiff implicitly holds the rule to a standard of zero risk,[8] whereas the Ninth Circuit has repeatedly emphasized that the "AHPA does not impose any requirement on USDA that all of its actions carry no associated increased risk of disease." 415 F.3d at 1094; see also id. at 1094 (finding that the imposition of "a requirement on USDA that its Final Rule present no additional risk to human or animal health" is a "misreading of the Animal

[7] Plaintiff relies on an October 2005 GAO report as evidence that violations of the feed ban occur. Pl. Memo. at 14-15. USDA has acknowledged that violations can occur, but the rule takes such incidents into account. Moreover, the GAO report primarily assessed "a small, discrete feed testing program" conducted by FDA beginning in August 2003. Pl. Exhibit 5 at 2. In concluding that the program could be improved, GAO acknowledged that it was only a "small part of FDA's BSE oversight effort and is one of several methods FDA uses to monitor for compliance with the feed-ban rule," id. at 3. In fact, a succession of GAO reports since 2002 demonstrates continuing improvements in FDA's oversight of the feed ban rule. The study, when put into proper perspective, should not be used, as the Ninth Circuit admonished, to "parse[] the regulations and fault[] USDA for any risk that a given step fail[s] to remove." 415 F.3d at 1096. Accordingly, this report does not present any significant new information that would undermine or call into question USDA's final rule.

[8] Plaintiff misrepresents USDA's position, as USDA has never said that there is an impenetrable barrier, but rather, that there is a "virtually impenetrable barrier," see, e.g., March 2, 2005 Transcript of Hearing on Application for Preliminary Injunction at 50, in other words, that the risks are small but "acceptable," 415 F.3d at 1100.

Health Protection Act"); id. at 1095 ("The structure of the AHPA is therefore inconsistent with the district court's strict requirement that the USDA regulation remove all risk of BSE entering the United States.").

Additionally, plaintiff continues to pursue its "'divide and conquer' strategy"of attacking each protective component of the regulatory system "in isolation" rather than evaluating "the cumulative effects of the multiple, interlocking safeguards" of USDA's comprehensive system of BSE prevention measures. 415 F.3d at 1095; see also id. at 1096 ("Instead of evaluating the BSE safeguards as part of a larger system, the district court [erroneously] parsed the regulations and faulted USDA for any risk that a given step failed to remove."). USDA has acknowledged that the system cannot be said to be perfect, and the rule anticipates imperfections and takes them into account. Indeed, even a rule banning all Canadian beef and cattle imports could result in violations, since no regulation is 100% effective.

Hence, the fact that an older animal or a few pregnant heifers were imported in violation of regulations does not warrant invalidating the rule.[9] See 9 C.F.R. § 93.436 (prohibiting the import of over-30-month cattle); 9 C.F.R. §§ 93.436, 95.4(d) (prohibiting import of pregnant heifers); see also 415 F.3d at 1089-90 (noting that "the Final Rule allowed the importation of Canadian cattle under 30 months of age provided the cattle were immediately slaughtered or fed and then slaughtered"); id. at 1099 ("USDA has made it abundantly clear that cattle may not be imported for breeding under the new regulations"). Similarly, plaintiff's reliance on a report issued by Public Citizen, Pl. Memo. at 16-17, is misplaced and the data referred to does not

[9] Neither of these isolated instances involved infected cattle or the risk of any spread of BSE. Canada took appropriate enforcement actions to ensure that violations did not occur.

demonstrate significant noncompliance with SRM removal requirements in domestic plants.[10]

Finally, plaintiff's reference to the Buschmann study, Pl. Memo. at 18-19, is unavailing. APHIS fully addressed the findings of this study in the Japanese beef final rule (70 FR 73906). APHIS found that the study, which was conducted by inoculating mice that were genetically engineered to be highly susceptible to BSE and to overexpress the BSE prion protein with positive tissues from a cow displaying clinical symptoms of BSE, was not directly applicable to cattle naturally infected with BSE.[11] Therefore, no changes were made in the final rule as a result

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[10] From January 2004, to May 2005, FSIS conducted approximately 8.8 million inspection procedures in over 6,000 federally inspected meat and poultry establishments to ensure that these establishments were complying with all applicable regulatory procedures. If inspectors found noncompliance with regulatory requirements, a Noncompliance Record (NR) was issued. The 1,036 NRs that were issued during this time frame for noncompliance with SRM removal requirements represent less than one percent of the total number of NRs issued for any reason during that time frame. Further, in addition to documenting the violation, FSIS inspectors verify that the product is made safe for human consumption or condemned. Based on this data, FSIS concluded that it is "confident it is successfully carrying out its mission to protect public health by strictly enforcing safeguards designed to protect Americans from BSE." This analysis can be found at: http://www.fsis.usda.gov/Fact_Sheets/BSE_Rules_Being_Strictly_Enforced/index.asp.

[11] The study found low levels of infectivity in the facial and sciatic nerves of the peripheral nervous system of the infected cow. These tissues resulted in infectivity when transferred to the genetically engineered mice. However, APHIS explained that the results of the study should be interpreted with caution for three reasons: (1) the findings could be influenced by the overexpression of prion proteins and may not accurately predict the natural distribution of BSE infectivity in cattle; (2) the route of transmission to the mice was both intracerebral and intraperitoneal, which are more effective in causing infectivity than oral consumption; and (3) the overexpression of prion proteins in transgenic mice may not accurately mimic the natural disease process. In addition, the fact that infectivity was demonstrated in a certain tissue through direct injection into overly sensitive mice cannot be interpreted to mean that the same tissue presents a significant risk to humans (where a significant species barrier exists). 70 Fed. Reg. 73906. This study has yet to be replicated, and no countries have changed the definition of SRM to include these tissues after this study was published.

of the study.[12]

CONCLUSION

Whether to hold oral argument on the summary judgment motions is a matter committed to the Court's discretion. Oral argument for the reasons advanced by plaintiff, however, should be denied.[13]

Dated: January 27, 2006

Respectfully submitted,

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[12] Based solely on an abstract rather than the complete study, plaintiff alleges that the Iwamaru study found BSE prions in the peripheral nerves of a bovine. Pl. Memo. at 19. According to the abstract, however, the study made no such finding. Rather, it detected only abnormal prion protein in the peripheral nerves, which does not necessarily indicate that the tissues were infective for BSE.

In urging the Court to take judicial notice of the McGarity law review article, plaintiff fails to point out that the Ninth Circuit cited this article, discussed it, and discounted it. 415 F.3d at 1087, 1100.

[13] Defendant objects to the filing of any reply by plaintiff in support of its motion. Plaintiff has already run afoul of the Federal Rules in presenting extra-record information to the Court, and their irrelevant and misleading allegations fail to provide even the slightest justification for holding a hearing on the exhaustively briefed summary judgment motions. Allowing them to file a reply would only perpetuate these transgressions and further waste the resources of the taxpayer and the Court.

JAMES J. GILLIGAN

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CERTIFICATE OF SERVICE

I certify that on January 27, 2006, a copy of Defendants' Opposition to Plaintiff's Motion to Set Motions for Summary Judgment for Oral Argument was served upon plaintiff's counsel by first-class mail, postage prepaid, as follows:

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